Remarks:

Applicants have cancelled claim 39, without prejudice. Applicants expressly reserve the right to pursue the cancelled subject matter in one or more subsequent applications that claim priority under 35 U.S.C. § 120 from this application.

Applicants have amended claims 1, 4, 8, 25, 29, 31, 34, and 38 to more particularly point out and distinctly claim the subject matter that they wish to prosecute in this application. Support for these claims is found throughout the application for exemplary locations: claims 1, 25, and 31: original claim 4; claims: 4, and 45: page 30, lines 3-8; and claims: 8, 29, and 38: page 9, lines 15-24.

None of these amendments adds new matter. Upon entry of the amendments, claims 1-38, and 40-48 will be pending. Of those claims, claims 10-24 are pending but withdrawn as being directed to a non-elected invention. Applicants request entry of the amendments and reconsideration of the pending claims.

Rejections Under 35 U.S.C. § 102

Claims 1-3, 5, 6, 8, 9, 25-27, 29-40, 42, 43, 45, 46, and 48 are rejected under 35 U.S.C. § 102(e), as allegedly anticipated by US2003/0138417 A1 as is evidenced by the SYNAGIS® product information sheet. The Examiner asserts that the '417 publication "teaches" a lyophilized human monoclonal IgG1 formulation in 20-60 mM of histidine. Applicants traverse in view of the claim amendments.

Claim 1, as amended, is directed to a solid formulation comprising at least one antibody, histidine, and arginine. The Examiner has acknowledged that the '417 application does not teach the use of arginine in a solid formulation. Accordingly, the rejection of claim 1 and the claims that depend from it should be withdrawn. Applicants assert the same argument for claim 25 as amended and dependent claims.

Claim 31, as amended, is directed to a liquid formulation comprising at least one antibody, histidine in a concentration of less than 30 mM, and arginine. The '417 application does not teach histidine in a concentration of less than 30 mM. Accordingly, the rejection of claim 31 and the claims that depend from it should be withdrawn.

Rejections Under 35 U.S.C. § 103(a)

Claims 1, 4, 7, and 28 are rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over US2003/0138417 in view of U.S. Pat. No. 5,580,856. The Examiner acknowledges that the '417 publication does not "teach" IgG2 antibody or the use of arginine in a lyophilized formulation. The Examiner asserts that the '856 patent teaches that a process of drying is often employed to stabilize proteins in a lypholized formulation for long-term storage. The Examiner alleges that one of ordinary skill would have been motivated and had a reasonable expectation of success combining the teachings of the '417 and '856 patents. Applicants respectfully traverse.

Claim 1, as amended, is directed to a solid formulation comprising at least one antibody, histidine, and arginine. Applicants do not believe that one of ordinary skill in the art would have been motivated or had a reasonable expectation of success in combining the use of histidine in a liquid solution with the use of arginine in a solid solution. Excipients used for freeze-dried protein formulations are selected for their ability to prevent protein denaturation during the freeze-drying process in addition to during storage (discussed on page 2). Some antibody stabilizers that are effective in liquid formulations are not effective in the much harsher freeze-dry process. Salts, for example, are effective in stabilizing antibodies in liquid but not in solid formulations. One of ordinary skill in the art would know that it is unpredictable whether an antibody stabilizer for liquid formulation will work for a lyophilized formulation and that further experimentation would be necessary to determine if an excipient combination successfully stabilizes in the lyophilized state. Accordingly, the rejection of claim 1 and the claims that depend from it should be withdrawn.

Claims 7 and 28 are directed to solid and liquid formulations, respectively, comprising IgG2 antibodies. The Examiner has acknowledged that the '417 application does not teach this subject matter. The '856 does not remedy this deficiency. Accordingly, the rejection of claims 7, and 28 should be withdrawn.

Claims 1, 41, and 47 are rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over US2003/0138417 and U.S. Pat. No. 5,580,856 in view of U.S. Pat. No.4,849,352. The Examiner acknowledges that the '417 publication and the '856 patent do not teach immunospecific antibody fragments. The Examiner states that the '352 patent "teaches a pharmaceutical composition comprising a polyclonal F(ab')2 that binds to any antigen, pepsin digested followed by ammonium sulfate precipitation". Applicants traverse in view of the claim amendments.

Claim 1, as amended, is directed to a solid formulation comprising at least one antibody, histidine, and arginine. Claim 41 is directed to the solid formulation of claim 1 wherein the antibody is an immunospecific antibody fragment. Claim 41 is not rendered

obvious for the reasons claim 1 is not obvious regardless of what the '352 patent may say about antibody fragments. The Examiner has acknowledged that the '417 and '856 applications do not teach the use of this subject matter. The '352 patent does not remedy this deficiency. None of the cited documents, thus, alone, or in any combination renders obvious the subject matter of claim 1. The rejection of claim 1 and the claims that depend from it should be withdrawn.

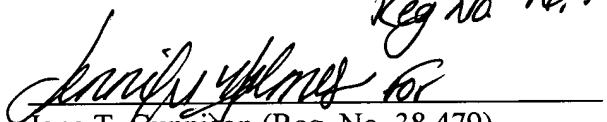
Claim 47, as amended, is directed to a liquid formulation comprising at least one antibody, histidine in a concentration of less than 30 mM, and arginine, wherein said antibody is an immunospecific antibody fragment. None of the cited documents teach or suggest the use of histidine in a concentration of less than 30 mM. For at least that reason, they cannot render claim 47 obvious. Accordingly, the rejection of claim 47 should be withdrawn.

In view of the foregoing, applicants request withdrawal of the rejections and allowance of the claims.

Applicant believes no fee other than the fee for the two month extension of time is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-1075, under Order No. ABGENIX.058A (ABX-HIS) from which the undersigned is authorized to draw.

Respectfully submitted,

Reg No 46,778



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